§ 522.315 Ceftiofur crystalline free acid.

(a) *Specifications*—(1) Each milliliter (mL) of suspension contains 100 milligrams (mg) ceftiofur equivalents (CE).

(2) Each mL of suspension contains 200 mg CE.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use*—(1) *Swine.* The formulation described in paragraph (a)(1) of this section is used as follows:

(i) *Amount.* 5.0 mg CE per kilogram (kg) of body weight by intramuscular injection in the postauricular region of the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis,* and *Streptococcus suis.*

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Following label use as a single treatment, a 14-day preslaughter withdrawal period is required.

(2) *Cattle.* The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount.* 6.6 mg CE per kg of body weight by a single, subcutaneous injection in the middle third of the posterior aspect of the ear.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD), shipping fever, pneumonia) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Haemophilus somnus.* For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica, P. multocida,* and *H. somnus.*

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

[68 FR 60296, Oct. 22, 2003, as amended at 69 FR 43892, July 23, 2004]

§ 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.

(a) [Reserved]

(b)(1) *Specifications.* Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution contains 42.5 milligrams of chloral hydrate, 8.86 milligrams of pentobarbital, and 21.2 milligrams of magnesium sulfate in each milliliter of sterile aqueous solution containing water, 33.8 percent propylene glycol, and 14.25 percent ethyl alcohol.

(2) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for general anesthesia and as a sedative-relaxant in cattle and horses.

(ii) For intravenous use only. The drug is administered at a dosage level of 20 to 50 milliliters per 100 pounds of body weight for general anesthesia until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. When used as a sedative-relaxant, it is administered at a level of one-fourth to one-half of the anesthetic dosage level.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 45 FR 16482, Mar. 14, 1980]

§ 522.390 Chloramphenicol injection.

(a) *Specifications.* Each milliliter contains 100 milligrams of chloramphenicol.

(b) *Sponsor.* See Nos. 000069 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Amount.* 5 to 15 milligrams per pound of body weight, intramuscularly or intravenously, every 6 hours. In severe infections, use 4 to 6 hour treatment intervals the first day. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.

(2) *Indications for use.* Treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsillitis caused by organisms susceptible to chloramphenicol.

(3) *Limitations.* Not for use in animals raised for food production. Federal law

restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992, as amended at 65 FR 45877, July 26, 2000]

§ 522.460 Cloprostenol sodium.

(a)(1) *Specifications.* Each milliliter of the aqueous solution contains 263 micrograms of cloprostenol sodium (equivalent to 250 micrograms of cloprostenol) in a sodium citrate, anhydrous citric acid and sodium chloride buffer containing 0.1 percent w/v chlorocresol B.P. as a bactericide.

(2) *Sponsor.* See Nos. 000061 and 068504 in § 510.600(c) of this chapter.

(3) *Conditions of use.* For intramuscular use in beef and dairy cattle to induce luteolysis.

(i) *Amount.* 2 milliliters (equivalent to 500 micrograms of cloprostenol).

(ii) *Indications.* (*a*) For scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.

(*1*) Single cloprostenol injection. Treat only animals with a mature corpus luteum. Estrus should occur in 2 to 5 days, and cattle should be inseminated at the usual time relative to the detection of estrus. If estrus is not observed, treated animals may be inseminated either once at 72 hours post injection or twice at 72 and 96 hours post injection.

(*2*) Double cloprostenol injection. Give cattle a second injection 11 days after the first injection. Estrus should occur 2 to 5 days after the second injection, and cattle should be inseminated at the usual time relative to the detection of estrus. If estrus is not observed, treated animals may be inseminated either once at about 72 hours post injection or twice at 72 and 96 hours following the second injection.

(*b*) Single cloprostenol injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 5 months after conception, or for treating unobserved (nondetected) estrus, mummified fetus, and luteal cysts.

(*c*) Single cloprostenol injection for the treatment of pyometra.

(iii) Do not administer to pregnant animals where the calf is not to be aborted.

(iv) Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Cloprostenol is readily absorbed through the skin and may cause abortion and/or bronchiospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 131.5 micrograms of cloprostenol sodium (equivalent to 125 micrograms of cloprostenol).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Special considerations.* Labeling shall bear the statements prescribed in paragraphs (a)(3) (iii) and (iv) of this section.

(4) *Conditions of use*—(i) *Amount.* 3 milliliters (equivalent to 375 micrograms of cloprostenol) intramuscularly per animal as a single dose.

(ii) *Indications for use.* To induce abortion in pregnant feedlot heifers from 1 week after mating until 4½ months of gestation.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 4678, Feb. 2, 1982, as amended at 48 FR 15619, Apr. 12, 1983; 49 FR 5100, Feb. 10, 1984; 49 FR 29957, July 25, 1984; 65 FR 6892, Feb. 11, 2000; 69 FR 40766, July 7, 2004]

§ 522.468 Colistimethate sodium powder for injection.

(a) *Specifications.* Each vial contains colistimethate sodium equivalent to 10 grams colistin activity and mannitol to be reconstituted with 62.5 milliliters sterile saline or sterile water for injection. The resulting solution contains colistimethate sodium equivalent to 133 milligrams per milliliter colistin activity.

(b) *Sponsor.* See 046573 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) 1- to 3-day-old chickens.

(i) *Dosage.* 0.2 milligram colistin activity per chicken.